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(54) IMPROVEMENTS IN PACKAGING

(71) We, PREBBLES (MEDICAL) LIMITED, a British Company of Bridge Street, Millers Bridge, Bootle, Merseyside L20 8NJ, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to the packaging in flexible containers, such as sachets, of quantities, most of ten metered quantities, of material, usually liquid, especially to such packaging of materials, e.g. pharmaceutical liquids, that are required to be heated, usually to produce a sterile condition thereof.

It is known to produce sachets of sterilised liquid in a controlled environment by filling preformed and presterilised laminated plastics film sachets with the presterilised liquid. In the packaging of materials which are liable to deterioration within a relatively short period of time once they are prepared or taken from bulk storage, say for or after dilution, the time taken to transfer them to sachets and seal the sachets, either imposes strict, even uneconomic, limitations on the quantity of liquid that can be prepared for one batch preparation, or requires a large number of filling stations to be in operation at the same time to ensure packaging of a reasonably large volume of prepared liquid within a restricted time period. As a result these known methods are slow and/or uneconomic to carry out.

As a preferred alternative, sterilisation may be performed as a separate operation. If done by irradiation or exposure to gases, results may well be superior to the presterilisation and controlled environment filling, but there are many materials to which such processes cannot be applied.

The most satisfactory sterilisation process is generally accepted to be controlled heating of filled containers to a specified temperature and for a specified time, for example in a steam autoclave. Whilst being successful with rigid containers this however, makes for severe problems with flexible containers, such as sachets, and not only from the point of view of finding materials capable of withstanding sterilising temperatures but also from the fact that the containers may be weakened and leak, or even burst, and that the combination of heat and consequent increased pressure within a sachet almost invariably results in a twisted and distorted form that appears unattractive and is usually virtually unsaleable.

It is an object of the present invention to overcome or at least reduce the impact of the problems associated with these known methods.

According to the invention there is provided a method or apparatus for producing flexible containers sealed and containing sterilised material, which method or apparatus includes the step of, or means for, heat-treating filled and sealed flexible containers in the presence of pressure that serves to reduce any tendencies of the containers to distort by reason of heat and internal pressure and is controlled at least partially by varying admission of air and/or steam, preferably on an on-off basis, to an enclosure within which the heat-treating step is affected, for example a steam filled autoclave.

Clearly the internal volume of each flexible container should exceed the volume occupied by the liquid contents under the conditions of temperature and pressure within an autoclave during sterilisation, and, preferably, the elevated external pressure for the sterilisation process should be at least sufficient to balance the internal pressure induced in the flexible container and at most insufficient to distort the container in a severely seam or joint-straining manner. In this way the fusion seals of a sachet or other flexible container will remain substantially unimpaired during sterilisation.

We have found that these pressure requirements are best met by controlled increase and decrease of pressure with rise and fall of temperature in a manner related

by experiments to the size and materials of the container, the relative volume and expansion characteristics of its contents, and the required treatment temperature. The above normal atmosphere pressure need not start until the temperature first nears or reaches that at which experience shows distortion first to occur, but should then rise with temperature either continuously or in steps as determined to avoid distortion, be held at maximum pressure until the sterilising time is over, and then be reduced as temperature falls.

Embodiments of the invention further contemplate forming sachets from laminated strip plastics film, filling the sachets as they are formed and sealing the sachets as they are filled, all in a continuous process, and prior to stereilising the contents of the filled and sealed sachets as mentioned above.

Preferably, apparatus embodying the invention comprises an autoclave with a steam heating and pressurising system including pressure control means for increasing pressure control means for increasing pressure during heat-up and decreasing it during cooling.

Specific implementation of the invention will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a diagrammatic illustration of one suitable process and apparatus; and

Figure 1A is a fragmentary view of a portion only of Figure 1.

In the drawings, two laminated heat resistant plastics webs, say of a nylon-polypropylene-polyethylene copolymeric material available under the trade name "Sterilite NP", are drawn by feed rollers 10 from supply reels 12 to be formed into a plurality of parallel, connected, tube-like formations 14 sealed relative to each other at 16 by heated discs 18. If desired, at least some preformation of the tubes 14 may be performed in the feed rollers 10 by corrugations therein, say in complementary shaped nip-type drive rollers.

Within each such tube 14 is a feed pipe 20 for material to be packed and such pipes may well have an exterior cross-sectional shape at least at the sealing discs 18 that further assists tube formation. The tubes extend from material metering means 22 connected to a reservoir 24 for the material to a filling position 26 for the delivery of predetermined quantities of material into the tubes immediately above a set of transversely extending, intermittently operable, heat sealing jaws 28 to complete formation of a desired sachet shape 30.

Thereafter the sachet shapes 30 are separated by cutting first parallel to the tube formations by rotary cutters 32, or stationary slitting blades, and then transversely thereto by blades 34, or a guillotine. The separated sachets 36 are then loaded Into an autoclave 38 equipped with a steam heating injection system 40 and a powerful blower fan 42 to ensure homogeneity of temperature and air/steam mixture through out th autoclave 38.

Clearly, any convenient alternatives to the sachet forming apparatus as a whole or components thereof may be used.

In operation of the autoclave 38, steam will be admitted to the injector system 40 via solenoid valve 44 and pressurising air via the solenoid valve 46 from compressor 48. If desired, of course, the air could be supplied to the injector system 40. As temperature rises within the autoclave it is accompanied by a predetermined pressure increase, typically to from 1 to 2 atmospheres above normal atmosphere, as required to preserve the shape of the sachets, using the solenoid controlled valves 44 and 46 in conjunction with a pressure sensor 50 and a temperature sensor 52. These sensors are shown at the fan end of the autoclave for convenience of illustration only. The desired pressure and temperature characteristics will be maintained via a suitable control system 54 operative relative to valves 44 and 46 and a solenoid valve 56 for venting.

In general, it has been found that a suitable pressure against time characteristic will have an upward curve that is gently concave, and any suitable control system 54, typically electrical or electronic circuitry, may be used. However the precise characteristic will, for particular sachets and sterilising temperatures, be determined by experiment. Normally, overpressure will only become necessary above a known intermediate temperature.

After attainment of the desired sterilising temperature, it will be maintained for a sttipulated time and then both temperature and overpressure reduced, usually following the same characteristic as for heat-up.

One suitable embodiment of the control system 54 utilises two contoured cards driven past respective electro-optic scanners say one for temperature control and another for pressure control. In turn those scanners are associated, respectively, with different co-ordinate drives, usually each transverse to the direction of card movement. Lines 58 and 60 from the sensors serve in providing appropriate scanner drive signals either directly or by way of transducing or signal translating devices of the control system 54. In this way, the contoured edges of the cards provide definitions of temperature/pressure characteristics relative to co-ordinate axes perpendicular to the card movement with the scanners in co-ordinate positions corresponding to actual conditions within the autoclave.

The temperature scanner may then control solenoid valve 44 in the steam supply via line 62 on an open/closed basis depending on whether or not the card obstructs the scanner, and the pressure scanner similarly controls solenoid valve 64 over line 64, with both scanners coupled in an OR manner to control the venting solenoid valve 56 over line 66.

Such an arrangement is capable of controlling entire cycles with any degree of desired phased operation of temperature and pressure, typically with maximum pressure application coinciding with or slightly preceding attainment of maximum temperature and persisting beyond onset of cooling, perhaps even beyond completion of cooling.

WHAT WE CLAIM IS:—

1. A method of producing sterile sealed flexible containers, including the step of heat-treating filled and sealed flexible containers in the presence of pressure that serves to reduce tendencies of the containers to distort by reason of heat and internal pressure and is controlled at least partially by varying admission of air and/or steam to an enclosure within which the heat-treating step is effected.

2. A method according to claim 1, wherein the admission of air and/or steam is controlled on an on-off basis.

3. A method according to claim 1 or claim 2, wherein venting of the enclosure is controlled on an on-off basis.

4. A method according to claim 1, 2 or 3, wherein the pressure reaches a value of from 1 to 2 atmospheres over normal atmospheric pressure.

5. A method according to any preceding claim, wherein said pressure is varied according to temperature.

6. A method according to any preceding claim, wherein said pressure is increased with temperature rise to sterilising temperature, maintained thereat for a predetermined time during which the sterilising temperature is maintained, and then reduced as cooling is effected.

7. Sealed flexible container sterilising apparatus when used for carrying out the method of claim 6, comprising au autoclave with a steam heating and pressurising system including pressure control means for increasing pressure during heat-up and decreasing it during cooling.

8. A method or apparatus according to any preceding claim wherein the flexible containers are sachets of laminated plastics material.

9. A method of producing sterial sealed flexible containers substantially as herein described with reference to the accompanying drawing.

10. Apparatus for producing sterial sealed flexible containers arranged and adapted to operate substantially as herein described with reference to and as shown in the accompanying drawing.

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COMPLETE SPECIFICATION

This drawing is a reproduction of the Original on a reduced scale.

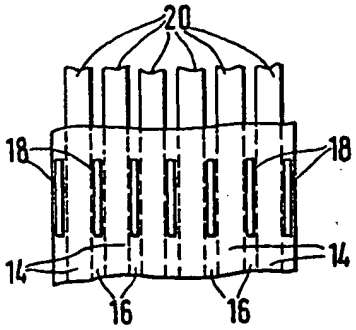

Fig.1A

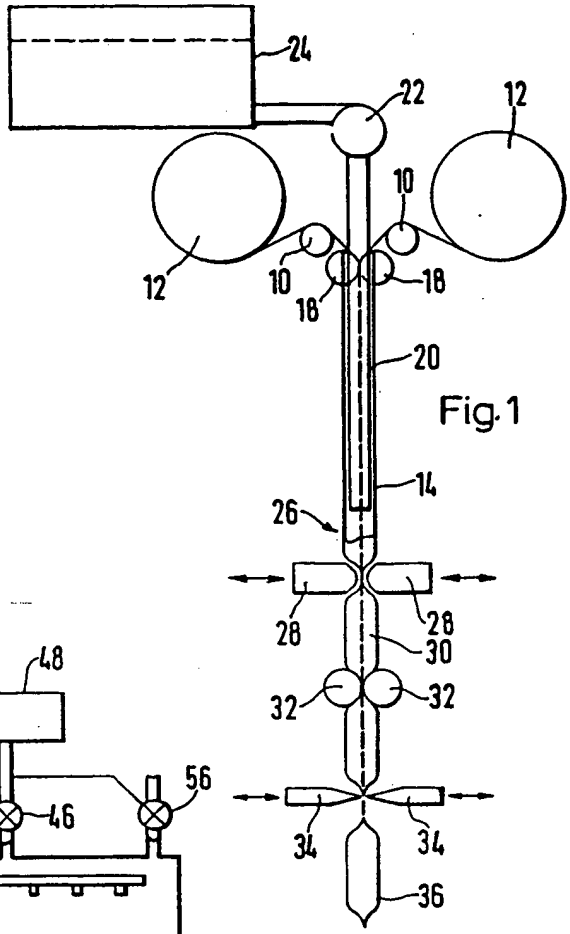

Fig.1